

this is up to the mfg. Co. and it is option that mfg. Publish theirs,
not a requirement.

(BBMDL 013372) (Highly Confidential).

4. B. Braun's AWP Manipulation Benefited Providers at the Expense of the Class

334. The purpose of B. Braun's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Braun understood, as reflected in a June 15, 1992 memorandum, that a higher AWP was "advantageous with payors who reimburse based on a cost plus arrangement." (BBMDL 008056) (Highly Confidential).

335. As evidenced by a September 18, 1996 e-mail, B. Braun recognized that manipulating AWP's to meet its competitors was "scandalous," "unethical" and "fraudulent":

I'm writing to you because of a potential problem for McGaw and a potentially larger problem for IVAX. It has to do with the method in which products are sold in our industry at a low actual price, and the wholesaler (our customer) bills Medicare for an arbitrary "average wholesale price." These prices are published in compendia such as Red Book and Blue Book.

I'm wondering if you saw the article in *Barron's* on June 10, 1996. This issue is described in great detail including the fact that the Justice Department is looking into the issue and the Inspector General of Medicare is investigating these practices.

I have held up authorizing the continuation of this practice at McGaw for quite a few months, but they're most anxious to continue the process as our sales are suffering. According to the article, some say that it is not illegal, but it is unethical. I am concerned that McGaw will no sooner increase its average wholesale prices to meet its competitors when the entire industry is going to get slammed for what may be perceived as scandalous, or worse, fraudulent practice of reimbursement.

(BBMDL 000011) (Highly Confidential).

336. Despite discussing and memorializing its concerns, B. Braun promptly proceeded to manipulate its AWP's and market the spread in an effort to match the competition.

a. In an internal memorandum dated December 20, 1996, a B. Braun employee states:

I evaluated each McGaw AWP against Baxter's and Abbott's and individually determined which AWP should be increased. . . . In general, I raised the McGaw AWP to make them equivalent to Baxter.

(BBMDL 009658) (Highly Confidential).

b. A second memorandum, created in October of 1997 reveals that B. Braun subsequently performed an analysis to "assure that McGaw AWP are in line with Baxter/Abbott AWP on competitive products." (BBMDL 009763) (Highly Confidential). In fact, an October 17, 1997 B. Braun memorandum reveals that the company increased 54 separate AWP following a review of 200 drugs to "make them equivalent to both Baxter and Abbott." (BBMDL 001891) (Highly Confidential). B. Braun increased the AWP of 29 drugs in 1996 for the same reason. (BBMDL 009658) (Highly Confidential).

337. B. Braun, through its employees and agents, also provided free samples of its drugs, and purported educational grants, to providers. The free samples and educational grants would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

338. In an October 30, 1998 memorandum addressing pricing strategies for its drug ProcalAmine, in lieu of a price reduction, B. Braun directs personnel to offer customers "something of value instead – for example, give them an educational grant, or sponsor a speaker[.]" The same memorandum also suggests that B. Braun employees might offer a "free case for every so many purchased" to match competitors' prices "without lowering" the price of its drug. (BBMDL 002088) (Highly Confidential).

5. Specific B. Braun AWP Documented by the DOJ

339. In a report published by the DHHS (the "DHHS Report"), the DOJ documented at least 23 instances where the published AWP for various dosages of 3 drugs manufactured by

B. Braun were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 3 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by B. Braun in the 2001 *Red Book*.

Drug	B. Braun's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Dextrose	\$11.28	\$1.61	\$9.67	601%
Dextrose Sodium Chloride	\$11.34	\$1.89	\$9.45	500%
Sodium Chloride	\$11.33	\$1.49	\$9.84	660%

6. Inflated AWP's From B. Braun Price Lists

340. In response to government subpoenas, B. Braun produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that B. Braun has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Table 1 are a number of those drugs (not already referenced above) and the substantial spread offered to a particular B. Braun customer.

341. Table 1 is an analysis of certain dosages of B. Braun drugs from a document entitled "PHARMCO." (BBMDL 011831) (Highly Confidential)).

Table 1

Drug	Gerimed Unit Price	AWP	\$ Diff AWP	% Spread
Intralipid	\$6.75	\$57.87	\$51.12	757%
Lactated Ringers 1000	\$1.02	\$11.87	\$10.85	1063%
Travasol	\$6.05	\$82.34	\$76.29	1260%

342. As set forth above, B. Braun's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

I. The BMS Group (Bristol-Myers, OTN and Apoteco)

343. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWP's. The specific drugs for which relief is sought in this case are identified in Appendix A and are as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BMS GROUP (Bristol-Myers, OTN and Apoteco)	Avapro	irbesartan	Antihypertensive Agent Used to treat hypertension
	Blenoxane	bleomycin sulfate	Antineoplastic Used in the treatment of various forms of cancer
	Buspar	buspirone hcl	Antianxiety Agent (Psychotherapeutic Agent) Used to treat certain anxiety disorders or to relieve the symptoms of anxiety
	Carboplatin	paraplatin	Antineoplastic Used to treat cancer of the ovaries
	Cefzil	cefprozil	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Coumadin	warfarin sodium	Anticoagulant (Blood Modifier) Used to promote clotting
	Cytosan	cyclophosphamide	Antineoplastic Used in the treatment of various forms of cancer
	Etopophos	etoposide phosphate	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Glucophage	metformin hcl	Antihyperglycemic Agent Used to treat a type 2 diabetes mellitus.
	Monopril	fosinopril sodium	Antihypertensive Agent; Vasodilator (Cardiovascular Agent) Used to treat hypertension
	Monopril HCT	fosinopril sodium & hydrochloro-thiazide	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and congestive heart failure
	Plavix	clopidogrel bisulfate	Antithrombotic Agent Used to lessen the chance of heart attack or stroke

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Rubex	doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
	Serzone	nefazodone hcl	Antidepressant (Psychotherapeutic Agent) Used to treat mental depression
	Taxol	paclitaxel	Antineoplastic Used in the treatment of various forms of cancer
	Tequin	gatifloxacin	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Vepesid	etoposide	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Videx EC	didanosine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		amphotercin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections

1. The BMS Group Has Been the Target of Government Investigations

344. In connection with its scheme to inflate AWP's, BMS has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, Office of Inspector General of the U.S. Department of Health and Human Services, Attorney General for the State of Texas, State of California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S. House of Representatives, Committee on Commerce. Defendant Apothecon has been investigated in connection with its scheme to inflate AWP's by at least the Office of Medicare Fraud and Elder Abuse, Office of Attorney General, State of Texas.

345. These investigations confirm that BMS engaged in an ongoing deliberate scheme to inflate AWP's. For example, by letter dated February 27, 2001 to BMS, Rep. Stark outlined numerous examples of illegal practices by BMS. Referring to a letter from Denis Kaszuba, a

senior pricing analyst at BMS to Medispan, dated August 10, 1992 (BMSAWP/0011247), Rep.

Stark noted:

Bristol has control over the AWP, DP, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWP for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

346. In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

2. The BMS Group Controls the Published AWP for Its Products

347. The BMS Group has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one BMS document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [*sic*] any other business unit of Bristol-Myers Squibb Company.

348. Other internal documents clearly indicate that BMS had direct control over the spread between its states wholesale price and the published AWP. A BMS office dispatch dated September 9, 1992 notes the need for a mark up of the AWP over the state wholesale price. "After reviewing the results of the wholesaler survey performed by Bristol Oncology . . we have determined that for those items with a labeler 0003, we will use a 1.25 mark-up and for those

items with the labeler 00015, we will use a 1.20 mark-up. We noticed too, that FDB and Redbook use a 1.20 for everything.” (BMSAWP/0011246).

3. BMS’s AWP Manipulation Benefited Providers at the Expense of the Class

349. BMS was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. Indeed, BMS was aware of and tracked the prices and AWP’s of its competitors in order to remain competitive. In an internal BMS memorandum, BMS identifies its competitors who sell etoposide (Gensia, Pharmacia, Abbott, Chiron, Ben Venue, Immunex and Astra) and their corresponding list price and AWP’s. (BMS3CA/000128).

350. BMS created AWP competitor analyses that tracked the AWP’s of its competitors’ relevant drugs, and used that data internally to propose suggested AWP’s for BMS drugs. One such competitor analysis set forth the competitor AWP’s for Atenolol with chlorthalidone and provided an “Apothecon suggested AWP” for each dosage. (BMS3CA/000648)

351. BMS clearly believed that the maintenance of a spread on its drugs was important in gaining and maintaining market share. In an internal BMS document, concerning its drug Vepacid (etoposide), BMS noted:

The Etopophos product file is significantly superior to that of etoposide injection Currently, physician practice can take advantage of the growing disparity between Vepesid’s list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician’s financial incentive for selecting the brand is largely diminished.

4. Specific BMS AWP’s Documented by the DOJ

352. In a report published by the DHHS, the DOJ documented numerous instances where the published AWP’s for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the BMS Group drugs identified by the DOJ and the spread associated with one

particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotercin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

353. Other sources reveal additional evidence of fraudulent AWP's for drugs manufactured and marketed by the BMS Group:

5. Other AWP's Related to VEPESID (etoposide)

354. The February 27, 2001 letter from Rep. Stark to BMS noted that as to BMS "... the manipulated discrepancies between [BMS's] inflated AWP's and DP's versus their true costs are staggering. For example, in the 2000 edition of the *Red Book*, Bristol reported an AWP of \$1296.64 for ... Vepesid (Etoposide) for injection ... while Bristol was actually offering to sell the exact same drug to [a large national group purchasing organization] for \$70.00." The difference noted by Rep. Stark represents a % 1,752 spread related to Vepesid.

6. Other AWP's Related to Blenoxane

355. BMS internal documents reveal that in 1995, BMS set the *Red Book* AWP for Blenoxane at \$276.29. At the same time, BMS was selling Blenoxane to oncologists practicing in St. Petersburg, Florida for only \$224.22. In 1996, BMS increased its reported AWP for Blenoxane to \$291.49, while continuing to sell the drug to oncologist for \$224.27. In 1997, BMS falsely reported that it had increased the AWP of Blenoxane to \$304.60, when in reality, BMS had lowered the price to oncologists to \$155.00. In 1998, BMS again reported a false AWP for Blenoxane of \$304.60 while further reducing the actual price to oncologists to \$140.00.

7. The BMS Group Provided Free Goods and Other Incentives

356. As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. Thus, for example, the BMS Group provided free Etopophos® to two Miami oncologists in exchange for their agreement to purchase other BMS Group cancer drugs. Similarly, other documents show that the BMS Group provided free Cytogards in order to create a lower-than-invoice cost to physicians that purchased other cancer drugs through OTN. (A Cytogard is a device that prevents spillage of intravenous administered treatments such as BMS's cancer drug Etopophos®.)

357. As set forth above, the BMS Group's scheme to inflate its reported AWP's, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

358. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWP's for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

359. The chart below sets forth five examples where the BMS Group deliberately inflated AWP's that it reported for BMS Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotercin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

360. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWP's – which the 1997 *Red Book* indicates were manufactured only by the BMS Group at that

time: Paraplatin® (carboplatin), Rubet® (doxorubicin hydrochloride), and Taxol® (paclitaxel). Sales of these inflated drugs were substantial. For example, Paclitaxel generated \$941 million in revenue for the BMS Group in 1997, and Carboplatin generated \$702 million in revenue in 2001.

361. The government's investigation uncovered other drugs for which the BMS Group was stating a fraudulent AWP. Specifically:

- a. In the 2000 edition of the *Red Book*, BMS reported an AWP of \$1296.64 for Vepesid (Etoposide) for injection while BMS was actually offering to sell the exact same drug to a large customer for only \$70.00.
- b. From 1995 through 1998 the *Red Book* listed AWP for BMS' Blenoxane 15u increased from \$276.29 to \$304.60, while the actual cost to physicians declined from \$224.22 to \$140.00, resulting in a spread of \$164.60 in 1998

362. An internal BMS Group document shows that the AWP set by the BMS Group for its drugs bears no relation to an *actual* wholesale price, and is greater than the highest price actually paid by providers. More specifically, in a discussion about lowering Vepesid's AWP in order to create sales for Etopophos, the BMS Group stated that the "AWP for Vepesid would be reduced from its current level to the highest bid price currently in the marketplace."

363. BMS Group documents also reveal that physicians were making medical decisions based on how much profit they could make from the AWP manipulated spread. In considering provider choice between BMS drugs Etopophos® and Vepesid® (Etoposide), the BMS Group noted that:

The Etopophos product file is significantly superior to that of etoposide injection Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

364. While the BMS Group and other Defendants have placed the blame for setting published AWP's on the publications in which the AWP's are contained, another BMS Group

document demonstrates that publications reporting AWP's had no discretion to set AWP's, and instead published verbatim the prices reported by the BMS Group and other Defendants. In the document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [sic] any other business unit of Bristol-Myers Squibb Company.

J. Dey

365. Dey engages in an organization-wide and deliberate scheme to inflate AWP's. Dey has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Dey for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
DEY		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		albuterol or albuterol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		cromolyn sodium	Antiallergic and Mast Cell Stabilizer Used to help prevent or treat the symptoms of seasonal or chronic allergic rhinitis
		ipratropium bromide	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		metaproterenol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers

1. Dey Has Been the Target of Government Investigations

366. In connection with its scheme to inflate AWP's, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts,

the Attorney General of the State of California, the Attorney General for the State of Texas, the Attorney General of the State of Connecticut, and the District Attorney for the County of Suffolk, New York State.

367. These investigations confirm that Dey has engaged in a deliberate scheme to inflate the published AWP's for many of its drugs. For instance, Dey's spread for albuterol sulfate, a drug that constituted 37 % of Dey's income in 1998, drastically increased between 1992 and 1998. In 1992, Dey's *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was \$32.30. McKesson's wholesale price for the drug was \$25.45 (a spread of \$ 6.85 or 27%). By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to \$30.25, while McKesson's wholesale price had plummeted to \$10.00 (a spread of \$20.25 or 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

368. The federal government is not the only entity to uncover Dey's scheme to inflate AWP's. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWP's, both state's Medicaid Programs have been defrauded by Dey for millions of dollars. Texas alleges that, between 1995 and 1999, it paid \$13.7 million for Dey's albuterol sulfate and ipratropium bromide, when it should have paid only \$8.7 million – an overcharge of \$5 million. West Virginia alleges that Dey and others manipulated the AWP to significantly overcharge state agencies and residents for several drugs, including albuterol, from at least 1995 through 2000.

369. In its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads between Dey's published AWP's and actual wholesale prices for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:

Drug	NDC #	Year	AWP	ACTUAL PRICE	SPREAD	% OVERCHARGE
ALBUTEROL	49502-0303-17	1996	\$21.70	\$3.25	\$18.45	488%
IPATROPIUM BORMIDE	49502-0685-03	2001	\$44.10	\$8.35	\$35.58	355%
IPATROPIUM BROMIDE	49502-0685-03	2000	\$44.10	\$11.45	\$32.65	239%
IPATROPIUM BROMIDE	49502-0685-03	1999	\$44.10	\$11.45	\$30.11	177%

2. Dey Controls the Published AWP for Its Products

370. Dey has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. Dey's own documents indicate that it initially set both the AWP and WAC for its products and also regularly approved subsequent AWP and WACs published by industry compendia. For example:

a. In a January 13, 1996 letter from Dey to First Data Bank, Day announced the availability of a new ipratropium bromide inhalation solution. The letter includes the following instructions to First Data Bank:

"Effective immediately, please update your database to reflect the introduction of this new DEY product as follows:

NDC/ Order Number	Description	Vial Size	Strength	Units per Ctn	Ctns per Case	AWP	WAC
49502-685-03	Ipratropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	25	12	\$44.10	\$25.50
49502-685-60	Ipratropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	60	12	\$105.60	\$60.90

(DL-CA00120) (Confidential)

b. In a 1998 worksheet produced by *Red Book* to Dey in order to verify its listings of Dey products, an employee of Dey went through each of the Dey products listed in the *Red Book* and approved each of the AWP and WACs for each of its products. Handwritten

comments on the document include the notation “9/11/98 – checked AWP & WAC pricing (backup attached)” (DL-CA 00080) (Confidential).

3. Dey’s AWP Manipulation Benefited Providers at the Expense of the Class

371. The purpose of Dey’s AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries. This is clear from Dey’s own documents. For example:

a. Dey was aware that its customers were “spread shopping” and competed by increasing the spread to its customers. In an internal worksheet filled out by Dey in preparation for a bid of potential sales to one of its customers, Dey listed the current contract price of various products as well as a recommended new contract price. In the notes next to these figures the worksheet states, “This account needs AWP-40% or better to see profit due to the employer groups they serve. Have not made the switch to our product line due to the spread . . .” (DL-TX-0014029)

b. Competition between generic products produced by Dey was fierce and the spread was a major factor in this competition. In another similar bid price worksheet for a different customer, the corresponding notes state “cromolyn pricing is at AWP-40% and 35% respectively – bear in mind that we are competing with the branded spread and the generic perception of [sic] everything should be AWP-60%” (DL-TX-0014439)

372. This competition came at the expense of Plaintiffs and the Class whose payments were based on AWP. For instance, Albuterol sulfate, a multisource drug and one of Dey’s top selling products, was a focus of the federal government’s investigation into AWP inflation. OIG found that “Medicare’s reimbursement amount for albuterol was nearly six times higher than the median catalog price” and that “Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to suppliers.” See “Excessive Medicare Reimbursement for Albuterol,” OEI-03-01-00410, March 2002.

373. The OIG determined that the Medicare-allowed amount for albuterol sulfate in 1996 was \$0.42. However the actual wholesale price was \$0.15, and the highest available wholesale price was \$0.21.

374. GAO also found that albuterol sulfate was one of a small number of products that accounted for a large portion of Medicare spending and volume. More specifically, albuterol sulfate ranked first in volume of units covered by Medicare, accounting for 65.8% of total units reimbursed. Furthermore, albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. *See* GAO Report to Congressional Committees, MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8.

4. Specific Dey AWP's Documented by the DOJ

375. In a report published by the DHHS, the DOJ documented at least 15 instances where the published AWP's for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

Drug in Lowest Dosage Form	2001 <i>Red Book</i> AWP	DOJ Determined AWP	Difference	Percentage Spread
Acetylcysteine	\$59.88	\$25.80	\$34.08	132%
Albuterol Sulfate	\$30.25	\$9.17	\$21.08	230%
Cromolyn Sodium	\$42.00	\$23.01	\$18.99	82%
Metaproterenol Sulfate	\$30.75	\$11.29	\$19.46	172%

5. Inflated Dey AWP's From Dey's Price Lists

376. According to Dey's own documents, the published AWP's for many of its own products were higher than the actual prices charged wholesalers and other intermediaries.

Table 1 below is excerpted from a pricing proposal by Dey to McKesson Drug Company, one of the county's largest wholesalers, dated December 20, 1995.

Table 1

Generic Name	Strength	Size	AWP	WAC	Suggested Sell Price	% Discount from WAC	% Spread
Acetylcysteine Solution	10%	4 mL	\$67.80	\$25.80	\$18.00	-40.0%	277%
Acetylcysteine Solution	10%	10 mL	\$40.26	\$15.27	\$13.50	-30.0%	198%
Acetylcysteine Solution	10%	30 mL	\$110.48	\$41.97	\$33.50	-35.0%	230%
Acetylcysteine Solution	20%	4 mL	\$81.36	\$31.08	\$21.50	-40.0%	278%
Acetylcysteine Solution	20%	10 mL	\$48.66	\$18.57	\$16.20	-30.0%	200%
Acetylcysteine Solution	20%	30 mL	\$133.43	\$50.64	\$39.90	-35.0%	234%
Acetylcysteine Solution	20%	100 mL	\$92.21	\$75.90	\$59.90	-40.0%	54%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$30.25	\$14.50	\$12.00	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$36.30	\$17.40	\$14.40	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$72.60	\$34.50	\$28.80	-28.7%	152%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$42.00	\$34.20	\$29.00	-25.0%	45%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$84.00	\$66.00	\$58.00	-22.3%	45%
Metaproterenol Sulfate Inhalation Soln.	0.4%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Metaproterenol Sulfate Inhalation Soln.	0.6%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Sodium Chloride Solution	0.9%	3 mL	\$24.20	\$13.00	\$10.94	-32.7%	121%
Sodium Chloride Solution	0.9%	5mL	\$24.20	\$13.00	\$10.94	-32.7%	121%

(DL-TX 0011179)

6. Dey Provided Free Goods and Other Incentives

377. In addition to marketing the spread, Dey has utilized other impermissible inducements to stimulate sales of its drugs without accounting for them in its WAC or AWP. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Dey provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

378. For example, in an announcement of a special incentive program to its customers to induce the purchase of its Ipratropium Bromide Inhalation solution, Dey sent its customers an offer sheet entitled "Profitability Enhancement For You" in which it stated "For every dollar of Dey Cromolyn Sodium unit-dose purchased, Dey will provide free goods of either: Coromolyn Sodium Inhalation Solution 0.02%, 2.5ml, at 1.0 times the rebate amount -OR- Ipratropium Bromide Inhalation Solution 0.02%, 2.5ml, when it launches, at a value of 1.5 times the rebate amount for Cromolyn." (DL-TX-0004775).

7. Dey Has Concealed Its AWP Manipulation

15. In an effort to conceal the existence of a spread from end payors, Dey concealed the true wholesale prices of its drugs. For instance, in a handwritten memorandum to Dey's pricing committee a potential pricing structure with a customer was discussed:

"I met with IPC to discuss our contract offer (illegible). . . Tom Konnelly (IPC) said he wanted to keep net pricing hidden from 3rd parties by increasing in the purchase price on our offer by 25%. IPC then requires a 25% rebate back to IPC. . . I have remarked the pricing. If this offer is accepted, the higher price will go into McKesson as a chargeback contract. Dey will then rebate IPC 25% on contract purchases on a quarterly basis. . ."

(DL-TX-0024844)

379. As set forth above, Dey's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

K. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

380. Fujisawa engages in an organization-wide and deliberate scheme to inflate AWP's. Fujisawa has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Fujisawa for which relief is sought in this case are set forth in Appendix A and are identified as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
FUJISAWA GROUP (Fujisawa Healthcare, Fujisawa Pharmaceutical and Fujisawa USA)	Aristocort	triamcinolone, triamcinolone diacetate or triamcinolone acetonide	Anti-Inflammatory, Steroidal; Used in the treatment of asthma
	Aristospan	triamcinolone hexacetonide	Anti-Inflammatory Agent, Steroidal Used to provide relief for inflamed areas of the body
	Cefizox	ceftizoxime sodium or ceftizoxime in d5w	Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Cyclocort	amcinonide	Anti-Inflammatory Agent Used to treat inflammatory symptoms of skin disorders
	Lyphocin	vancomycin hydrochloride	Antibacterial Agent Used to treat infections in many different parts of the body
	Nebupent	pentamidine isothionate	Antiprotozoal Agent Used to try to prevent Pneumocystis carinii pneumonia
	Pentam 300	pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
	Prograf	tacrolimus	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
		acyclovir sodium	Antiviral Agent Used to treat herpes simplex infections, varicella-zoster (chickenpox) in people with weakened immune systems, and severe genital herpes infections
		dexamethasone sodium phosphate	Anti-Inflammatory Agent; Antiemetic (Gastrointestinal Agent) Used in various applications to treat inflamed areas of the body
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
		fluorouracil	Antineoplastic Used to treat cancer, including colon, rectum, breast, stomach, and pancreas
		gentamicin sulfate	Antibacterial Agent Used to treat serious bacterial infections
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

1. Fujisawa Has Been the Target of Government Investigations

381. In connection with its scheme to inflate AWP, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

2. Fujisawa Controls the Published AWP for Its Products

382. Fujisawa controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on March 10, 1997, Fujisawa provided MediSpan with an updated listing of pack prices – including AWP – for all of its products. (FJ-MDL 015152-015159).

3. Fujisawa's AWP Manipulation Benefited Providers at the Expense of the Class

383. The purpose of Fujisawa's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Fujisawa understood that providers and intermediaries sought significant AWP spreads. In a March 1995 Monthly Report, dated March 30, 1995, Fujisawa noted:

We have lost our Vanco business at Chartwell. They have recently been handed an edict to order those products with the largest spread between acquisition cost and AWP. Abbott has unbelievably high Vanco AWP. In an effort to counter this loss I suggested we look at picking up the Cefazolin business where our AWP for one gram Cefazolin is over \$8. Unfortunately our 10 gram price does not follow the same formula and is in the \$45 range while Schein is approximately \$58. We do however have a shot at Cefizox for Medicaid/Medicare patients which make up 50% of Chartwell's patients. Medicaid does not reimburse Chartwell for the Rocephin they currently use and while they will not reimburse for Cefizox either they could acquire Cefizox at a fraction of the cost. They use \$400,000 in Rocephin annually, \$200,000 for Medicaid/Medicare patients. That works out to better than \$100K in savings for Chartwell.

(FJ-MDL 005687-88) (Confidential).

384. Fujisawa, in a conscious effort to increase the spread for providers and intermediaries, changed its AWP and marketing practices accordingly. In a May 1995 Monthly Report, dated May 30, 1995, Fujisawa addressed its recent decision to increase its AWP for Vancomycin Hydrochloride and aggressively market the resulting spread increase:

Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business. As I have previously reported, some companies are still using AWP for reimbursement purposes. Chartwell has been told to search for the largest spread and order accordingly. I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at \$1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is \$163 and their contract is \$30 and if our AWP is \$162 we will have to be at least \$29 to have the same spread. Follow?

(FY-MDL 005668-69) (Confidential).

385. In an October 5, 1993 interoffice memorandum discussing Fujisawa's communications with industry pricing compendia, Fujisawa acknowledged that the AWP for nearly all of its products is inflated at least 33% over direct list prices:

One of the issues regarding our companies AWP listing is that the databases only use our listing as a "Suggested Manufacturers AWP". The standard wholesaler mark-up used by those databases is currently at 25% above direct list price which is our hospital list. Almost all of our products are at 33% or higher above list price.

(FJ-MDL 008346) (Confidential).

386. Further, just as Fujisawa motivates providers to administer drugs based on the AWP, Fujisawa rewards PBMs based on the degree of influence they exert to drive utilization of Fujisawa products. (FJ-MDL 010272-78) (Confidential).

4. Specific Fujisawa AWP's Documented by the DOJ

387. In a report published by the DHHS (AB-00-86), the DOJ documented at least 35 instances where the published AWP's for various dosages of 6 drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. The chart below sets forth

the 6 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Fujisawa in the 2001 *Red Book*.

Drug	The Fujisawa Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$565.10 ²	\$371.50	\$193.60	52%
Dexamethasone Sodium Phosphate	\$1.04 ³	\$.66	\$.38	58%
Fluorouracil	\$2.87	\$1.20	\$1.67	139%
Gentamycin Sulfate	\$12.64 ⁴	\$5.40	\$7.24	134%
Pentamidine Isethionate	\$98.75	\$36.00	\$62.75	174%
Vancomycin Hydrochloride	\$10.97 ⁵	\$7.00	\$3.97	57%

(P006299-006316).

5. Inflated AWP's From Fujisawa Price Lists

388. In response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spreads offered to each specific customer here is not practical.

389. Set forth below in Table 1, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa customer price list dated August 24, 1995, and their associated AWP spread. (FJ-MDL 013079-81) (Confidential).

² Calculation based on the AWP listed in the 1998 *Red Book*.

³ Calculation based on the AWP listed in the 1998 *Red Book*.

⁴ Calculation based on the AWP listed in the 1998 *Red Book*.

⁵ Calculation based on the AWP listed in the 1998 *Red Book*.

Table 1

Drug	Contract Price	AWP	\$ Diff AWP	% Spread
Triamcinolone	\$14.33	\$17.95	\$3.62	25%
Calcium Gluconate	\$11.50	\$34.00	\$22.50	196%
Cefazolin Sodium	\$139.00	\$367.13	\$228.13	164%
Ceftizoxime Sodium	\$7.50	\$11.86	\$4.36	58%
Amcinonide	\$41.50	\$52.13	\$10.63	26%
Doxycycline Hyclate	\$15.00	\$73.75	\$58.75	392%
Fluphenazine Hydrochloride	\$24.10	\$30.25	\$6.15	25%
Folic Acid	\$7.25	\$11.85	\$4.26	63%
Levothyroxine Sodium	\$3.90	\$38.43	\$34.53	885%
Lidocaine Hydrochloride	\$17.00	\$24.50	\$7.50	44%
Magnesium Sulfate	\$22.00	\$138.25	\$116.25	528%
Mannitol	\$28.00	\$56.50	\$28.50	101%
Neostigmine Methylsulfate	\$8.20	\$89.30	\$81.10	989%
Oxytocin	\$13.50	\$24.50	\$11.00	81%
Potassium Acetate	\$92.00	\$312.40	\$220.40	240%
Potassium Chloride	\$12.25	\$30.50	\$18.25	149%
Potassium Phosphate	\$30.25	\$133.75	\$103.50	342%
Pyridoxine Hydrochloride	\$35.00	\$47.00	\$12.00	34%
Scopolamine Hydrobromide	\$22.00	\$30.00	\$8.00	36%
Selenium	\$18.25	\$195.25	\$177.00	970%

390. Set forth below in Table 2, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa price list dated November 5, 1996, and their associated AWP spread. (FJ-MDL 008240-53) (Confidential).

Table 2

Drug	Wholesaler Price	AWP	\$ Diff AWP	% Spread
Adenocard IV	\$21.95	\$26.34	\$4.39	20%
Adenoscan	\$179.00	\$223.75	\$44.75	25%
Aristocort A	\$7.05	\$8.46	\$1.41	20%
Atropine Sulfate Injection	\$.64	\$1.12	\$.48	75%
Doxorubicin	\$12.44	\$45.50	\$33.06	266%
Furosemide	\$.74	\$.98	\$.24	32%

Drug	Wholesaler Price	AWP	\$ Diff AWP	% Spread
Hydroxyzine Hydrochloride	\$.42	\$.65	\$.23	55%
Protamine Sulfate	\$3.33	\$5.32	\$1.99	60%
Selepen	\$18.24	\$29.93	\$11.68	64%
Sodium Acetate	\$8.81	\$14.63	\$5.82	66%
Sodium Bicarbonate	\$2.04	\$3.33	\$1.29	63%
Sodium Chloride	\$.68	\$1.40	\$.72	106%
Sodium Phosphate	\$5.81	\$9.08	\$3.27	56%
Tracelyte	\$8.26	\$11.57	\$3.31	40%
Vinblastine Sulfate	\$26.50	\$43.23	\$16.73	63%
Water for Injection	\$1.10	\$2.34	\$1.24	113%

391. As set forth above, Fujisawa's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

L. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

392. The GSK Group has engaged in an organization-wide and deliberate scheme to inflate AWP's. The GSK Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs manufactured and/or distributed by the GSK Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
GSK GROUP (SmithKline Beecham, GlaxoSmithKline and Glaxo Wellcome)	Advair Diskus	salmeterol- fluticasone	Bronchodilator (Respiratory Agent) Used for treatment of asthma
	Agenerase	amprenavir	Antiviral Agent Used in treatment of HIV infection
	Alkeran	melphalan	Antineoplastic Used to treat ovarian cancer and a certain type of cancer in the bone marrow
	Amerge	naratriptan succinate	Antimigraine Agent Used for treatment of migraine attacks
	Beconase AQ	beclomethasone dipropionate monohydrate	Anti-Inflammatory Agent Used to treat discomfort of hay fever, other allergies, and other nasal problems

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Ceftin	cefuroxime axetil	Antibacterial Agent Used to treat infections caused by bacteria
	Combivir	lamivudine- zidovudine	Antiviral Agent Used in treatment of HIV infection
	Daraprim	pyrimethamine	Antiprotozoal Used for treatment of malaria and other protozoal infections
	Epivir	lamivudine	Antiviral Agent Used in treatment of HIV infection
	Flonase	fluticasone propionate (nasal)	Anti-Inflammatory Agent Used for treatment of allergic and nonallergic rhinitis
	Flovent	fluticasone propionate (inh)	Antiasthmatic (Anti-Inflammatory Agent) Used for treatment of asthma
	Imitrex	sumatriptan or sumatriptan succinate	Antimigraine Agent Used for treatment of migraine attacks or cluster headaches
	Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after chemotherapy
	Lamictal	lamotrigine	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Lanoxin	digoxin	Antiarrhythmic Agent (Cardiovascular Agent) Used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat.
	Leukeran	chlorambucil	Alkylating Agent (Antineoplastic) Used to treat cancer of the blood and lymph system
	Mepron	atovaquone	Antiprotozoal Used to treat and to prevent pneumonia
	Myleran	busulfan	Antineoplastic Used to treat some kinds of cancer of the blood.
	Navelbine	vinorelbine tartrate	Antineoplastic Used for treatment of lung cancer
	Paxil	paroxetine hcl	Antianxiety agent; Antidepressant (Psychotherapeutic Agent) Used in the treatment of various psychotherapeutic disorders
	Purinethol	mercaptopurine	Antimetabolite (Antineoplastic) Used to treat some kinds of cancer.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Relenza	zanamivir	Antiviral Agent Used in the treatment of the infection caused by the flu virus (influenza A and influenza B).
	Retrovir	zidovudine	Antiviral Agent Used for treatment of HIV infection
	Serevent	salmeterol xinofoate	Bronchodilator (Respiratory Agent) Used to treat or prevent symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
	Trizivir	abacavir sulfate-lamivudine-zidovudine	Antiviral Agent Used for treatment of HIV-1 infection
	Valtrex	valacyclovir hcl	Antiviral Agent Used for treatment of shingles and genital herpes
	Ventolin HFA	albuterol sulfate	Bronchodilator (Respiratory Agent) Used for treatment or prevention of bronchospasm
	Wellbutrin	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used for treatment of depression
	Zantac	rantidine hydrochloride	Gastrointestinal Agent Used in the treatment of active duodenal ulcer
	Ziagen	abacavir sulfate	Anti Infective Agent Used in the treatment of HIV infection
	Zofran	ondansetron hcl	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zofran ODT	ondansetron	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zovirax	acyclovir	Antiviral Agent Used for treatment of shingles, genital herpes and herpes simplex
	Zyban	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used to relieve mental depression. Also used to aid in cessation of smoking
		thioguanine	Antineoplastic Used to treat some kinds of cancer

1. The GSK Group Has Been the Target of Government Investigations

393. In connection with its scheme to inflate AWP's, the GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the

Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the Attorney General for the State of Nevada, Medicaid Fraud Control Unit.

394. These investigations confirm that the GSK Group has engaged in a deliberate scheme to inflate the published AWP for its drugs.

2. The GSK Group's Definition and Understanding of AWP

395. In a GSK document entitled "Zofran Tablets & Zofran Injection: Sales Training Guide Reimbursement Module" (GSK-MDL-ZN02-035925) (Highly Confidential), GSK defines AWP as follows:

Average Wholesale Price (AWP): The composite wholesale prices charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book and used by third-party payers as a basis for reimbursement.

(GSK-MDL-ZN02-035985) (Highly Confidential). Thus, by its own definition, GSK recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWP directly affect the payments made by the Class.

3. The GSK Group Controls the Published AWP for Its Products

396. The GSK Group has controlled and set the AWP for its pharmaceutical products during the Class Period. As set forth below, any claim that The GSK Group only reports a WAC to industry compendia and therefore is not responsible for the published AWP is belied by its own documents. For example:

a. In 1991 a Glaxo document entitled "Zofran Third Party Payment Plan," among the many recommendations concerning the pricing of its then new drug Zofran was the recommendation that "In establishing direct-to-wholesaler and *Red Book* wholesale prices for Zofran, Glaxo should take into consideration physicians' expected profit margins." (GSK-MDL-ZN02-03428) (Highly Confidential).

b. Expanding further on the recommendation above, elsewhere in the same document it is stated: “Because insurers often reimburse physician-infused drugs up to the average wholesale price (AWP), the doctor’s profits are determined by the differential between the AWP and the price they pay to the wholesaler or pharmacy supplier. The company should ensure that doctors will make acceptable return on Zofran® by managing markups through the distribution chain.” (GSK-MDL-ZN02-034366) (Highly Confidential).

397. As do all of the Defendants, GSK has direct control over the “markups” in the distribution chain for its products. That control results from an ability to set the published AWP.

4. The GSK Group’s AWP Manipulation Benefited Providers at the Expense of Plaintiffs and the Class

398. GSK acknowledged that the AWP, as published in industry compendia, was used as the basis for most payments by third party payors. GSK’s own documents state, “Most, but not all, plans determine a payment for new drugs, based on the drug’s cost as listed in the *Red Book* and pay all providers that amount less any patient co-payments.” (GSK-MDL-ZN02-035965) (Highly Confidential). Elsewhere in the same document GSK acknowledges: “Payment amounts for most payers is usually based on the AWP as listed in *Red Book*, however, co-payments, especially for Zofran Tablets will be required.” (GSK-MDL-ZN02-035973) (Highly Confidential).

399. The purpose of The GSK Group’s AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. That scheme has resulted in a system where drugs are administered based upon a profit incentive to physicians and other intermediaries and which results in an incentive to prescribe more expensive, rather than cheaper drugs. In talking points prepared in advance of negotiations with clinics, Glaxo instructed its sales people to remind customers that “Cheaper is not necessarily a prudent medical or business decision” and that “Cheaper ? Good medicine or Good Business!” (GSK-MDL-ZN02-077818-19) (Highly Confidential).

400. The GSK Group tried to maximize spread because it understood that its customers routinely engaged in “spread shopping” – comparing its AWP’s with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread).

401. Perhaps the most flagrant example of the GSK Group’s fraudulent manipulation of AWP’s is found in the documents relating to Glaxo’s Zofran® and SKB’s Kytril®. These two drugs both minimize the nausea associated with chemotherapy, and, prior to the merger of Glaxo and SKB, competed head-to-head in the same market. As detailed below, much of that competition concerned which product could generate *the greater spread*, or profit, for physicians; not over which product was better for patients.

5. Glaxo’s Zofran®

402. A Glaxo marketing document, sent to its sales and marketing personnel via U.S. Mail and interstate wire facilities, advises that they should emphasize to medical providers both the benefits of Zofran® and the financial benefits of the spread. Specifically:

By using a 32 mg bag, the physician provides the most effective dose to the patient and increases his or her profit by \$_____ in reimbursement as well as paying no upcharges for the bag or admixing

403. A follow-up internal Glaxo memo, dated October 27, 1994, entitled “Zofran Pricing Recommendation,” states: “Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP.” The memo later notes that “Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement.” (P007015-P007490, at P007487-P007490).

404. In response to the larger spread being offered on Kytril, this same internal document discusses several options to increase Zofran’s spread “to balance the reimbursement

spread which currently exists between Zofran and the market in which it competes. . . .” The pricing options considered for increasing the “spread” for Zofran® included:

Recommendation #1

4.5% price increase	\$178.97 to \$187.02
Increase AWP	16 2/3% to 20% \$214.76 to \$233.78 (8.5%)
3% Wholesaler Rebate (11/14/94 - 1/31/95)	\$187.02 to \$172.92 (chargeback) \$179.92 to \$167.31 (rebate)

405. In an effort to hide the fact that Glaxo was increasing the spread for Zofran®, Glaxo elected to not only increase its AWP and provide rebates, but to also include a small actual price increase. In describing the reason for an increase in the actual selling price, an internal Glaxo document states:

The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

406. Glaxo internal documents, however, recognized that as a result of its increasing the spread for Zofran®, SKB would have two options:

- Option 1: Decrease the purchase price of Kytril.
- Option 2: Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than \$52.00.

(P007015-P007490, at P007489-P007490).

407. In order to increase the spread for Zofran®, Glaxo increased the AWP for a 20 ml injection of Zofran® to \$233.02 in January of 1995. This was discussed in an October 27, 1994 memo entitled “Zofran Pricing Recommendation” and further discussed at a Glaxo pricing committee meeting on November 4, 1994. (P007015-P007490, at P007487-P007490).

408. In February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices. Specifically:

Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at \$233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

Letter from Bliley, Chairman Commerce Committee to Nancy Min DeParle, Sept. 25, 2000 (P007015-P007490, at P007046).

409. Glaxo was fully aware that the larger spread for its product would be a big selling point. A flier in GSK's possession but produced by wholesaler NSS advertises to physicians that:

Your Zofran™ Deal Just Got Better!!!

(Effective 4:00pm January 9, 1995)

*New AWP \$233.02

New Price from NSS

** \$161.00 * *

(GSK-MDL-ZN02-034942) (Highly Confidential).

410. In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

(P007015-P007490, at P007078).

411. In a Glaxo internal memo dated October 25, 1994, entitled "Issue considerations on Zofran pricing strategies," Nancy Pekarek (a communications manager for Glaxo who later became Vice-President of U.S. Corporate Media Relations) recognized the implications of increasing the AWP to create a better spread:

If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:

(1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran-perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?

If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.

(2) Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? *What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government?* How will this new pricing structure compare with costs in other countries?

(3) *Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy. How will they be affected? What response do we have for them?*

(GSK-MDL-Z01-05675) (Highly Confidential) (emphasis added).

412. Glaxo also knew that Zofran® products were being marketed based on the spread between the actual cost and the published AWP. For example, when Glaxo introduced the Zofran® premixed IV bag, it used marketing materials which stated:

Convenient
Costs Less Than Vial
Higher AWP
Better Reimbursement

(P007015-007490, at P007243).

413. Other internal Glaxo documents directly compared the “Profit Per Dose” and “Profit as %” and “Profit Per Vial” of Zofran® to Kytril®. These comparisons also identified that in order to increase the spread for Zofran®, Glaxo included “early pay disc” and “rebates” and “incentive.”

414. In marketing the new Zofran® premixed IV bag, Glaxo produced and used a document entitled “Profit Maximization – It’s In the Bag.” This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo’s marketing materials including the following chart:

	Cost	AWP	Potential Reimbursement/ Patient	Reimbursement/ Year	ROI
Zofran 32mg bag	\$110.41	\$195.00	84.59	\$13,957,350	76.6%
Kytril 1 mg vial	\$102.73	\$175.00	72.27	\$11,924,000	70.3%

(P007114) (Highly Confidential).

415. Another Glaxo document entitled “Profit Maximization – Continued” reflects how much “Total Revenue Potential” there was for using Zofran® because of the large spread between the cost and reimbursement for various Zofran® products. (P007115) (Highly Confidential).

416. An internal SKB document further acknowledges Glaxo’s attempts to use and market the spread and its effects on the Class:

As of late, Glaxo promotional efforts have focused almost entirely on the financial benefits of “up-dosing” rather than efficacy of Zofran. *Though physicians have certainly benefited financially from such tactics, it is costing 3rd party payers and patients more for medication.*

(P007115-P007490, at P007138-P007139) (Highly Confidential) (emphasis added).

417. In a September 27, 2000 article in *USA Today*, Glaxo spokesman Rick Sluder (who received a copy of the October 24, 1994 memo described herein) discussed the issue of the spread and blamed a system that set up a reimbursement method that relies on average wholesale prices which are not actually “representative of actual prices.” Mr. Sluder, admitting that Glaxo changed its wholesale prices to keep up with competitors who changed wholesale prices, stated “We didn't want to put ourselves at a price disadvantage.” Mr. Sluder also admitted that the marketing of Glaxo drugs is based, in part, on the spread. In fact, he noted that Glaxo's sales staff is briefed on the price advantages to doctors who bill and get reimbursed based upon the AWP. (E-mail from Clapton to Vaughan dated Sept. 27, 2000 citing “How Drug Makers Influence Medicare Reimbursements to Doctors; WALL STREET JOURNAL (P007501-P007506).

6. SKB's Kytril

418. According to its internal documents (and prior to selling Kytril®'s global rights to the Roche Group in December 2000), SKB also knew that by creating the spread for Kytril®, it could directly affect the amount of revenue medical providers receive and thereby affect overall demand for Kytril®. Specifically, an August 6, 1996 internal SKB memo stated:

In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP.

* * *

From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.

(P007015-P007490, at P007249-P007250).

419. Internal SKB documents reveal how it marketed the spread. One internal document entitled “Price Comparison of Kytril and Zofran for Reimbursement” discussed how

much additional revenue and “spread per patient” a medical provider would make by using Kytril® due to its larger spread. It stated:

Kytril reimbursement for 5 patients treated \$540.00 - Kytril 6 treated patients \$423.12

Difference = \$117.00 every 6 patients.

Use 5ht3 5 times a day = \$2,340.00 month. \$28,080.00 year more!

(P007015-P007490, at P007117).

420. Other internal SKB documents entitled “Cost v. Profit” and “Kytril Profit Model” compare Kytril® and Zofran® to demonstrate how much additional profit/revenue the medical provider will receive by using Kytril®.

7. General Counsel Correspondence Between Glaxo and SKB

421. Most revealing is an exchange of correspondence between counsel for Glaxo and SKB over Zofran® and Kytril® in which each accuse the other of fraud.

422. On February 6, 1995, Timothy D. Proctor, Senior Vice President, General Counsel and Secretary for Glaxo, sent a letter to J. Charles Wakerly, Senior Vice President, Director and General Counsel of SKB informing him of “several issues pertaining to the advertising and marketing of Kytril”:

Glaxo’s sales representatives have encountered a substantial amount of what appear to be “homemade” Kytril vs. Zofran cost comparisons. It is our understanding that many of these pieces have been generated through a company-provided lap top computer program.

....

In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their “profits” from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F) but charge Medicaid for three vials. This raises significant fraud and abuse issues which I am sure you will want to investigate.”

(P007015-P007490, at P007123-P007126).

423. On February 22, 1995, Ursualy B. Bartels, Vice President and Associate General Counsel for SKB, wrote in response that SKB was investigating Glaxo's claims and asked whether Glaxo had specific information regarding the improper marketing of Kytril. Mr. Bartels also accused Glaxo of using false and misleading marketing materials regarding Zofran that rely on the medical providers' ability to garner more profit. Specifically, he stated:

Regarding similar concerns, we would like to draw your attention to reports we are receiving from our field force regarding reimbursement issues. In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate available to wholesalers on all non-hospital Zofran sales on the multi-dose vial. *The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP.* Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. *Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors. In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.*

(P007015-007490, at P007478-P007481) (emphasis added).

424. On April 25, 1995, Adrianna L. Carter, Glaxo Assistant General Counsel, responded to SKB's February 22, 1995 letter. Ms. Carter provided, pursuant to SKB's request, numerous additional examples of false and misleading marketing materials concerning "cost comparisons distributed to health care professionals by SmithKline representatives." Ms. Carter also denied SKB's allegations regarding "fraud and abuse" over the price increase of Zofran. However, Ms. Carter did admit that the AWP price increase for Zofran® does not affect the

actual cost to medical providers and that Glaxo's sales representatives were using the "spread" to gain market share. Specifically, Ms. Carter stated:

It is true that, despite a price increase, some physicians and other healthcare professionals will not see the higher price as the result of rebates or other incentives.

* * *

It is also true that our sales representatives have been explaining the relationship between the price and Medicare reimbursement for Zofran to physicians.

* * *

Finally, Ms. Carter stated that despite SKB's assertions that any alleged improper marketing of Kytril would end, "Unfortunately, despite your efforts, these activities are still ongoing."

(P007015-007490, at P007127-P007131).

425. The fact that Glaxo and SKB each accused the other of similar conduct, but neither took any action to bring it to the attention of the public or the appropriate authorities, is evidence that each of them were engaged in an ongoing scheme to defraud the Plaintiffs and Class.

8. Other Improper Incentives

426. In addition to marketing the spread on its products, the GSK Group has also used other methods to induce physicians and other intermediaries to use its drugs such as rebates and free samples in order to increase the spread between acquisition costs and reimbursement.

427. In an e-mail by GSK account representative Paul J. Ostruszka explaining how he was able to increase the market share of Zofran over Anzimet, among the suggested techniques he recommends to his fellow GSK account reps is "Ask your customers how much JUST 1 FREE Zofran Tablet Sample is WORTH" (emphasis in original). This e-mail was later forwarded to the entire Zofran team. (GSK-MDL-ZN02-077634).

428. An advertisement in the *Florida Infusion Chemo net* reveals that SKB created the spread not only by artificially inflating the AWP for Kytril®, but also by providing discounts and rebates. Specifically, the advertisement states:

We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion.

(P007015-007490, at P007187).

429. SKB also knew that medical providers were billing Plaintiffs and the Class for a 1 mg single dose vial per patient, but actually were using less than the full single dose per patient. Depending on the weight of a patient, medical providers were able to use less of the drug, *i.e.*, the lighter the patient, the less Kytril® was needed. SKB subsequently introduced a Kytril® 4 mg Multi-Dose vial that allowed medical providers to bill 6 treatments for the cost of 4. For example, an SKB marketing document entitled "Kytril Vial Usage" states, "You can use only three vials of Kytril for four patients." (P007015-007490, at P007068 and P007455).

430. SKB also used other financial incentives to decrease medical providers' costs and thereby increase profits. For example, SKB promised to contribute to research and education programs through the OnCare Foundation if OnCare agreed to use Kytril instead of a competing drug. (P007015-007490, at P007061).

9. Specific GSK Group AWP's Documented by the DOJ

431. In a report published by the DHHS (the "DHHS Report"), the DOJ documented that the published AWP's for various dosages of Zofran and Kytril manufactured by The GSK Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the AWP's identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The GSK Group in the 2001 *Red Book*.

Drug	GSK 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Ondanestron (Zofran)	\$128.24	\$22.61	\$101.63	450%
Granisetron (Kytril)	\$195.20	\$139.04	56.16	40%

(P006299-P006316).

432. As set forth above, the GSK Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

M. Immunex

433. Immunex engages in an organization-wide and deliberate scheme to inflate AWP's. Immunex has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of Immunex for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
IMMUNEX	Leukine	sargamostin	Antineutropenic Agent Used to help produce bone marrow and white blood cells
	Novantrone	mitoxane hydrochloride	Antineoplastic Used in the treatment of multiple sclerosis and various forms of cancer
	Thioplex	lyophilized thiotepa	Antineoplastic Used in the treatment of ovarian and breast cancer, lymphoma and bladder tumors
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer

1. Immunex Has Been the Target of Government Investigations

434. In connection with its scheme to inflate AWP's, Immunex has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of

Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

2. Immunex Definition and Understanding of AWP

435. Immunex's internal documents reveal that it understood how industry compendia defined and utilized AWP:

Red Book Definition of AWP

The average wholesale price as we consider it here at Red Book is the price a retail hospital or pharmacy pays if purchases product from wholesaler before the discount if any.

Blue Book Definition of AWP

AWP represents an average price which a wholesaler would charge a pharmacy for a particular product.

(IAWP002238) (Highly Confidential).

3. Immunex Controls the Published AWP for its Products

436. Immunex controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In 2000, in the midst of numerous government investigations concerning AWP manipulation, Immunex denied responsibility for controlling the published AWP for its products. For example, in an October 26, 2000 letter to *Red Book*, Immunex states in pertinent part:

As requested, enclosed please find an updated summary of list pricing and package information for Immunex products. Please note that Immunex Corporation is not responsible for setting the Average Wholesale Price (AWP). Therefore, we do not set or approve AWP information for any Immunex products.

(IAWP023473) (Highly Confidential). Previously, in a 1996 interview, an Immunex spokesperson had informed Barron's that "drug manufacturers have no control over the AWP published." (IAWP003071) (Hooked on Drugs," *Barron's*, Jun. 10, 1996).

437. Immunex's internal documents, however, establish that it controlled the AWP for all of its products throughout the Class Period. For example:

a. A January 12, 1996 letter from *Red Book* to Immunex, in pertinent part, states:

This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system.

(IAWP008102) (Highly Confidential).

b. A January 12, 1995 letter from Immunex to *Red Book* states:

Below you will find a list of new suggested Average Wholesale Prices (AWPs) for selected Immunex products, along with a new NDC ... all effective January 10, 1995 ... Please update your databases accordingly. A new copy of Immunex's Average Wholesale Price Product Pricing Guide will be sent to you next week.

(IAWP016500) (Highly Confidential).

4. Immunex's AWP Manipulation Benefited Providers at the Expense of the Class

438. The purpose of Immunex's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Immunex understood that providers and intermediaries were reimbursed at AWP – and benefited from a larger spread.

a. In an internal document entitled "Health Care Policy Fast Facts," created in 1995, Immunex urged its sales personnel to remember "[p]hysician's offices use their own charge schedule for billing purposes, and get reimbursed at AWP, based on the published prices in the pricing databases." (IAWP012961) (Highly Confidential).

b. Recently, in a January 3, 2000 interoffice memo, Immunex discussed the significant revenues to be made by providers which used its Leucovorin and Methotrexate products. Specifically, Immunex stated that, "Leucovorin and Methotrexate represent significant revenue sources for the physician office or clinic. Due to the 'spread' (difference between